

I CLAIM:

1. A composite elastic material useful for prosthetic applications, comprising:  
at least one cured silicone elastomer layer containing silicone oil; and  
hollow microspheres dispersed throughout the elastomer layer.
2. The composite elastic material as claimed in claim 1, including an elasticized fabric layer intimately bonded to one side of the silicone elastomer layer.
3. The composite elastic material as claimed in claim 2, wherein said composite elastic material is in the form of a tubular prosthetic suction liner having a closed distal end, and dimensioned and configured so as to be rollable onto a distal end of a residual limb of a prosthetic device user.
4. The composite elastic material as claimed in claim 2, wherein said composite elastic material is in the form of a tubular sleeve open at opposed ends with the silicone elastomer layer covering the inside wall of the sleeve and the elasticized fabric covering the exterior of the sleeve.
5. The composite elastic material as claimed in claim 3, including a distension controlling reinforcement matrix embedded in the silicone elastomer layer over a distal end area of the suction liner, said matrix containing reinforcement elements that provide substantial stiffness against elongation of the liner in a direction along the liner length and which do not provide substantial resistance against distension of the silicone elastomer layer in directions transverse to the liner length.
6. The composite elastic material as claimed in claim 3, wherein said reinforcement matrix is a knit textile having anisotropic distension properties along orthogonal directions, such that the textile is relatively inextensible in a first direction and is relatively freely extensible in an orthogonal direction.
7. The composite elastic material as claimed in claim 3, including a rigid

prosthetic connector element attached to the distal end of said liner, said connector element arranged to engage and retain a prosthetic pin connector usable by a prosthetic user, said connector element embedded in a cured silicone elastomer distal end cap adhered to the distal end of said suction liner and providing access to a prosthetic pin connector.

8. The composite elastic material as claimed in any one of claims 3, 5, 6 or 7, wherein said suction liner is tapered inwardly towards its distal end, and wherein the liner has a circular outer wall having radii of curvature centered along a liner first longitudinal axis of external symmetry extending longitudinally centrally within the liner; a circular curved inside anterior wall portion extending along a liner length, and having first radii of curvature centered on a second longitudinal axis of anterior curvature extending longitudinally along said liner length and a circular curved inside posterior wall portion having second radii of curvature centered on a third longitudinal axis of posterior curvature extending along said liner length, said first, second and third longitudinal axes lying in a common longitudinally and transversely extending plane bisecting the interior and posterior wall portions, and wherein said second and third axes are spaced apart a predetermined offset distance on opposed sides of said first axis to thereby define an interior wall portion that is thicker along said liner length than the posterior portion; and further wherein said anterior and posterior wall portions intersect each other along said liner length on the liner interior along diametrically opposed inner transition wall portions that extend tangentially relative to the adjoining anterior and posterior wall portions along said liner length, whereby the interior wall of the suction liner along the inner transition wall portions are free of rapid changes in thickness, curvature or cross-section profile.

9. The composite elastic material as claimed in claim 8, wherein said second and third radii are equal to each other along their respective second and third axes.

10. The composite elastic material as claimed in claim 8, wherein an interior proximal flange area of said interior wall portion is tapered radially outwardly and an exterior proximal flange area of said posterior wall portion is tapered radially inwardly.

11. The composite elastic material as claimed in claim 8, including a spherical curved inside distal wall portion of said suction liner, said distal wall portion joining the adjoining interior wall of the suction liner along a tangency that forms a smooth transition between the inside distal wall portion and the adjoining interior wall of the suction liner, and further wherein the adjoining wall of the suction liner is circular in cross-section and has a center of curvature located on said first axis; and further wherein the thickness of the wall of the suction liner adjoining said spherical curved distal wall portion is uniform and equal to the thickness of said anterior wall portion.

12. The composite elastic material as claimed in one of claims 2, 3, 4, 5, 6 or 7, including a second cured silicone elastomer layer between the at least one silicone elastomer layer and the elasticized fabric layer, said second silicone elastomer layer partially penetrating and being embedded in said textile layer on one side thereof so as to form a continuous coating on said one side, and adhered to said at least one silicone elastomer layer on the opposite side of the second silicone elastomer layer.

13. The composite elastic material as claimed in claim 4, wherein said elasticized fabric layer is a normally porous, air permeable material that has been rendered non-air permeable by a second silicone cured elastomer layer, said second silicone elastomer layer forming a relatively thin coating as compared with the elasticized fabric layer on said one side of said fabric layer.

14. The composite elastic material as claimed in claim 4, wherein said elasticized fabric layer comprises a rectangular section of flat elasticized fabric that is folded into a tube and is sewn together along one side of the tube along abutting longitudinally extending edges of the fabric.

15. The composite elastic material as claimed in claim 1, 2, 3, 4, 5, 6 or 7, wherein the composite elastic material has a minimum tensile strength of one Pa and a 100% modulus of 5 to 30 kPa.

16. The composite elastic material as claimed in claim 15, wherein the elasticized

fabric is supplex Nylon jersey knit, 28 needles per 2.5 cm, comprising 87% Nylon, 13% Spandex, said fabric substantially stretchable beyond its relaxed dimensions both lengthwise and widthwise.

17. The composite elastic material as claimed in claim 4, wherein the elasticized fabric is circular rib knit of 95% Nylon and 5% Lycra, 220 needles per 2.5 cm in 12 cm width and 264 needles per 2.5 cm in 14 cm width, from Rx Textile.

18. The composite elastic material as claimed in claim 1, 2, 3, 4, 5, 6 or 7, wherein said microspheres are expanded polymeric shells.

19. The composite elastic material as claimed in claim 1, 2, 3, 4, 5, 6 or 7, wherein said microspheres have a density of .005 g/cm<sup>3</sup> to 1.25 g/cm<sup>3</sup>.

20. The composite elastic material as claimed in claim 19, wherein said microspheres have a density of .05 g/cm<sup>3</sup>.

21. The composite elastic material as claimed in claim 1, 2, 3, 4, 5, 6 or 7, wherein said at least one silicone elastomer layer comprises, by weight:

50 - 99.4% silicone elastomer

.5 - 45% silicone oil

.1 - 5% microspheres.

22. The composite elastic material as claimed in claim 21, wherein the ratios of silicone elastomer, silicone oil and microspheres are as follows, by weight:

77.25% silicone elastomer

10% silicone oil

.75% microspheres.

23. The composite elastic material as claimed in any one of claims 1 - 7, including one or more skin treatment agents blended with the silicone elastomer.

24. The composite elastic material as claimed in claim 23, wherein the skin treatment agent consists of Vaseline, said Vaseline present in an amount of up to 15% by weight of the silicone elastomer layer.

25. The composite elastic material as claimed in claim 23 wherein the skin treatment agent comprises Vaseline and aloe vera.

26. The composite elastic material as claimed in claim 25, wherein the aloe vera constitutes 3% by weight of the at least one silicone elastomer layer and the balance of the skin treatment agents is Vaseline, said skin treatment agents constituting up to 20% by weight of the silicone elastomer layer.

27. The composite elastic material as claimed in any one of claims 1 - 7, wherein the at least one silicone elastomer layer has the following properties:

Density	:	.5 g/cm <sup>3</sup> to 1.3 g/cm <sup>3</sup>
Tensile Strength	:	.1 Pa minimum
Durometer (00)	:	13 - 62
100% Modulus	:	5 kPa to 250 kPa
Compression Set	:	0 to 30

28. The composite elastic material as claimed in claim 27, wherein the silicone elastomer layer has the following properties:

Density	:	.94 g/cm <sup>3</sup>
Tensile Strength	:	.5 Pa
Durometer (00)	:	22
100% Modulus	:	20 kPa
Compression Set	:	8

29. The composite elastic material as claimed in claim 3, wherein the at least one silicone elastomer layer comprises by weight:

77.25% CF13-2188 NuSil Technology Silicone Elastomer;

10% Baysilone Fluid M350 silicone oil of GE Bayer Silicones GmbH;

11.9% Medical grade type WebCo 71 Vaseline of Shell;  
.75% Expance expanded 551DE microspheres of AKZO NOBEL; and  
.1% Aloe Vera Pure Beauty oil of Jason Natural Cosmetics, product 78522-04001.

30. The composite elastic material as claimed in claim 3, wherein the at least one silicone elastomer layer comprises by weight:

77.25% CF13-2188 NuSil Technology Silicone Elastomer;  
10% Baysilone Fluid M350 silicone oil of GE Bayer Silicones GmbH;  
11.9% Medical grade type WebCo 71 Vaseline of Shell;  
.75% Expance expanded 551DE microspheres of AKZO NOBEL;  
.1% Aloe Vera Pure Beauty oil of Jason Natural Cosmetics, product 78522-04001;

and further including a cured silicone elastomer distal end cap adhered to the distal outer end of said suction liner, said end cap formed of MED-4950 or MED-4050 or CF 15-2188 of NuSil Technology and 2% by weight of coloring powder.

31. A composite elastic material useful for prosthetic applications comprising:

an elasticized knit textile fabric having a thickness, and being substantially stretchable lengthwise and widthwise relative to its relaxed dimensions, and configured as a continuous circular tube;

a continuous coating of cured silicone elastomer on one side of the fabric, said coating only partially penetrating the fabric thickness and being partially embedded in said fabric, the thickness of said coating being relatively thin as compared with the thickness of the fabric; said silicone elastomer coating being fully elastically stretchable at least to the same extent as said fabric.

32. A composite elastic material as claimed in claim 31, including a tubular length of assembled reinforcing fibers having anisotropic distension properties in the axial lengthwise and the radial widthwise directions secured to one end of said tube, such that said fibers collectively have substantially higher stiffness against elongation in the lengthwise direction than in the widthwise direction relative to the tube lengthwise

direction, said fibers being free of said silicone elastomer coating.

33. A suction liner having proximal and distal ends and tapering inwardly towards its distal end, said liner including a molded silicone elastomer inner wall, a circular outer wall having radii of curvature centered along a liner first longitudinal axis of external symmetry extending longitudinally centrally within the liner; said inner wall including a circular curved inside anterior wall portion extending along a liner length and having first radii of curvature centered on a second longitudinal axis of anterior curvature extending longitudinally along said liner length, and a circular curved inside posterior wall portion having second radii of curvature centered on a third longitudinal axis of posterior curvature extending along said liner length, said first, second and third longitudinal axes lying in a common longitudinally and transversely extending plane bisecting the interior and posterior wall portions, and wherein said second and third axes are spaced apart a predetermine offset distance on opposed sides of said first axis to thereby define an anterior wall portion that is thicker along said liner length than the posterior portion; and further wherein said anterior and posterior wall portions intersect each other along said liner length on the liner interior along diametrically opposed inner transition wall portions that extend tangentially relative to the adjoining anterior and posterior wall portions along said liner length, whereby the interior wall of the suction liner along the inner transition wall portions are free of rapid changes in thickness, curvature or cross-section profile.

34. The suction liner as claimed in claim 33, wherein said second and third radii are equal to each other along their respective second and third axes.

35. The suction liner as claimed in claim 33 or 34, including a spherical curved inside distal wall portion of said suction liner, said distal wall portion joining the adjoining interior wall of the suction liner along a tangency that forms a smooth transition between the inside distal wall portion and the adjoining interior wall of the suction liner, and further wherein the adjoining wall of the suction liner is circular in cross-section and has a center of curvature located on said first axis; and further wherein the thickness of the wall of the suction liner adjoining said spherical curved distal wall portion is uniform and equal to the thickness of said anterior wall portion.

36. The composite elastic material as claimed in claim 5 or 6, including a rigid prosthetic connector element attached to the distal end of said liner, said connector element arranged to engage and retain a prosthetic pin connector usable by a prosthetic user, said connector element embedded in a cured silicone elastomer distal end cap adhered to the distal end of said suction liner and providing access to a prosthetic pin connector.

37. The composite elastic material as claimed in claim 9, wherein an interior proximal flange area of said interior wall portion is tapered radially outwardly and an exterior proximal flange area of said posterior wall portion is tapered radially inwardly.

38. The composite elastic material as claimed in claim 9 or 10, including a spherical curved inside distal wall portion of said suction liner, said distal wall portion joining the adjoining interior wall of the suction liner along a tangency that forms a smooth transition between the inside distal wall portion and the adjoining interior wall of the suction liner, and further wherein the adjoining wall of the suction liner is circular in cross-section and has a center of curvature located on said first axis; and further wherein the thickness of the wall of the suction liner adjoining said spherical curved distal wall portion is uniform and equal to the thickness of said anterior wall portion.

39. The composite elastic material as claimed in claim 8, including a second cured silicone elastomer layer between the at least one silicone elastomer layer and the elasticized fabric layer, said second silicone elastomer layer partially penetrating and being embedded in said textile layer on one side thereof so as to form a continuous coating on said one side, and adhered to said at least one silicone elastomer layer on the opposite side of the second silicone elastomer layer.

40. The composite elastic material as claimed in claim 12, wherein said elasticized fabric layer is a normally porous, air permeable material that has been rendered non-air permeable by a second silicone cured elastomer layer, said second silicone elastomer layer forming a relatively thin coating as compared with the elasticized fabric layer on said one said of said fabric layer.

41. The composite elastic material as claimed in claim 8, wherein the composite elastic material has a minimum tensile strength of one Pa and a 100% modulus of 5 to 30 kPa.